

GAU 1655

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March 21, 2001

FILE: ARCD:307USD1



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Commissioner for Patents
Washington, DC 20231

RE: SN 09/768,877 "METHODS OF TREATMENT OF TYPE 2 DIABETES" – Kenneth S. Polonsky, et al.

Sir:

, Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/10100104/GNS.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Gina N Shishima
Reg. No. 45,104

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Encl.: As noted

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Gina N. Shishima

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kenneth S. Polonsky, *et al.*

Serial No.: 09/768,877

Filed: January 23, 2001

For: METHODS OF TREATMENT OF TYPE 2
DIABETES

Group Art Unit: 1655

Examiner: J. Enewold Goldberg

Atty. Dkt. No.: ARCD:307USD1/GNS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

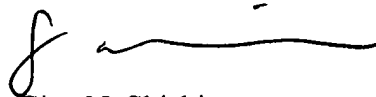
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The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/10100104/GNS.

This application is a divisional application of Serial No. 09/422,869, filed October 21, 1999, and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/422,869.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Form PTO-1449 (modified)

Atty. Docket No.

ARCD:307USD1/GNS

Serial No.

09/768,877

List of Patents and Publications for Applicant's

Applicant

Kenneth S. Polonsky *et al.*

INFORMATION DISCLOSURE STATEMENT

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Filing Date:

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Foreign Patent Documents

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U.S. Patents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,545,672	08/13/96	Knutson	514	603	07/08/94

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 98/11254	3/19/98	PCT			
	B2	WO 96/09317	03/28/96	PCT			
	B3	WO 00/09709	02/24/00	PCT			

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Barnes and Hodgkin, "The <i>tra-3</i> sex determination gene of <i>Caenorhabditis elegans</i> encodes a member of the calpain regulatory protease family," <i>EMBO J.</i> , 15(17):4477-4484, 1996.
	C2	Barrett <i>et al.</i> , "L-trans-epoxysuccinyl-leucylamido(4-guanidino)butane (E-64) and its analogues as inhibitors of cysteine proteinases including cathepsins B, H and L," <i>Biochem J.</i> , 201:189-198, 1982.
	C3	Carafoli and Molinari, "Calpain: a protease in search of a function?", <i>Biochem. Biophys. Res. Commun.</i> , 247:193-203, 1998.
	C4	Ciccarese <i>et al.</i> , "Preliminary data on a genome search in NIDDM siblings: the NIDDM 1 locus on chromosome 2 is not linked to NIDM in the Sardinian population", <i>Diabetologia</i> , 40:1366-1367, 1997.
	C5	Dear <i>et al.</i> , "A new subfamily of vertebrate calpains lacking a calmodulin-like domain: implications for calpain regulation and evolution", <i>Genomics</i> , 45:175-184, 1997.
	C6	Emori <i>et al.</i> , "Endogenous inhibitor for calcium-dependent cysteine protease contains four internal repeats that could be responsible for its multiple reactive sites", <i>Proc. Natl. Acad. Sci. USA</i> 84:3590-3594, 1987.

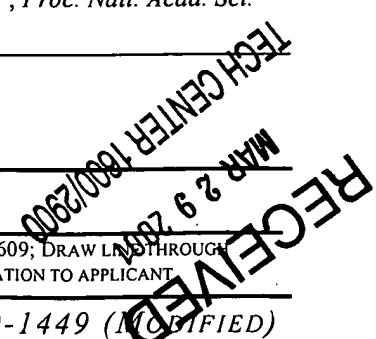
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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)



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List of Patents and Publications for Applicant's

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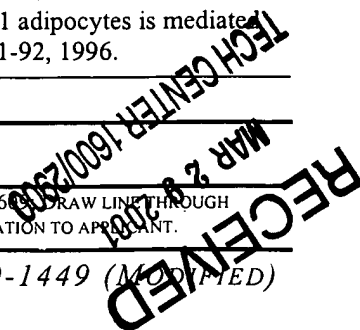
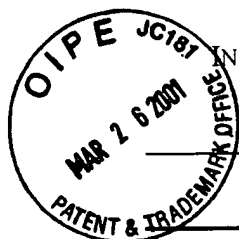
Exam. Init.	Ref. Des.	Citation
	C7	Figueiredo-Pereira <i>et al.</i> , "Comparison of the effect of calpain inhibitors on two extralysosomal proteinases: the multicatalytic proteinase complex and m-calpain", <i>J Neurochem</i> , 62:1989-94, 1994.
	C8	Flexner, "HIV-protease inhibitors," <i>N. Engl. J. Med.</i> , 338:1281-1292, 1998.
	C9	Ghosh <i>et al.</i> , "A large sample of Finnish diabetic sib-pairs reveals no evidence for a non-insulin-dependent diabetes mellitus susceptibility locus at 2qter", <i>J. Clin. Invest.</i> , 102:704-709, 1998.
	C10	Hani <i>et al.</i> , "Mapping NIDDM susceptibility loci in French families: studies with markers in the region of <i>NIDDM1</i> on chromosome 2q," <i>Diabetes</i> , 46:1225-1226, 1997.
	C11	Hanis <i>et al.</i> , "A genome-wide search for human non-insulin-dependent (type 2) diabetes genes reveals a major susceptibility locus on chromosome 2," <i>Nature Genet.</i> , 13:161-166, 1996.
	C12	Hashida <i>et al.</i> , "Inhibitions by E-64 derivatives of rat liver cathepsin B and cathepsin L <i>in vitro</i> and <i>in vivo</i> ," <i>J. Biochem</i> , 88:1805-1811, 1980.
	C13	Jackson <i>et al.</i> , "Obesity and impaired prohormone processing associated with mutations in the human prohormone convertase 1 gene", <i>Nature Genet.</i> , 16:303-306, 1997.
	C14	Mahtani <i>et al.</i> , "Mapping of a gene for type 2 diabetes associated with an insulin secretion defect by a genome scan in Finnish families", <i>Nature Genet.</i> , 14:90-94, 1996.
	C15	Naggert <i>et al.</i> , "Hyperproinsulinaemia in obese fat/fat mice associated with a carboxypeptidase E mutation which reduces enzyme activity", <i>Nature Genet.</i> , 10:135-141, 1995.
	C16	O'Dowd <i>et al.</i> , "Discovery of three novel G-protein-coupled receptor genes", <i>Genomics</i> , 47:310-313, 1998.
	C17	Posmantur <i>et al.</i> , "A calpain inhibitor attenuates cortical cytoskeletal protein loss after experimental traumatic brain injury in the rat", <i>Neuroscience</i> , 77:875-88, 1997.
	C18	Richard <i>et al.</i> , "Mutations in the proteolytic enzyme calpain 3 cause limb-girdle muscular dystrophy type 2A", <i>Cell</i> , 81:27-40, 1995.
	C19	Saido <i>et al.</i> , "Calpain: new perspectives in molecular diversity and physiological-pathological involvement," <i>FASEB J.</i> , 8:814-822, 1994.
	C20	Smith <i>et al.</i> , "The insulin-induced down-regulation of IRS-1 in 3T3-L1 adipocytes is mediated by a calcium-dependent thiol protease", <i>Mol. Cell. Endocrinol.</i> , 122:81-92, 1996.

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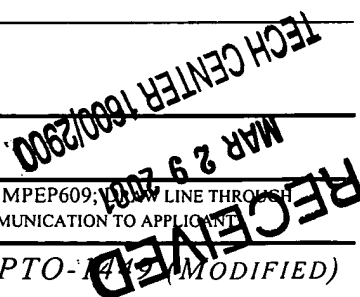
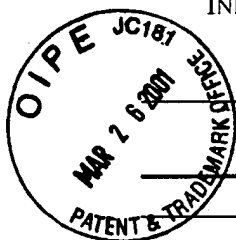
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	C21	Spielman and Ewens, "A sibship test for linkage in the presence of association: the sib transmission/disequilibrium test", <i>Am. J. Hum. Genet.</i> , 62:450-458, 1998.
	C22	Thomas <i>et al.</i> , "Genetic linkage study of a major susceptibility locus (D2S125) in a British population of non-insulin dependent diabetic sib-pairs using a simple non-isotopic screening method," <i>Hum. Genet.</i> , 101:212-213, 1997.
	C23	Tsujinaka <i>et al.</i> , "Synthesis of a new cell penetrating calpain inhibitor calpeptin," ABSTRACT, <i>Biochem. and Biophys. Res. Comm.</i> , 153(3): 1201-1208, 1988.
	C24	Ueda <i>et al.</i> , "Evidence for the participation of the proteasome and calpain in early phases of muscle cell differentiation", <i>Int. J. Biochem. Cell Biol.</i> , 30:679-94, 1998.
	C25	Villa <i>et al.</i> , "Calpain inhibitors, but not caspase inhibitors, prevent actin proteolysis and DNA fragmentation during apoptosis", <i>J. Cell. Sci.</i> , 111:713-22, 1998.
	C26	Waxman and Krebs, "Identification of two protease inhibitors from bovine cardiac muscle," <i>J. Biol. Chem.</i> 253:5888-5891, 1978.
	C27	Zimmerman <i>et al.</i> , "Inhibition of secretion from isolated rat alveolar epithelial type II cells by the cell permeant calpain inhibitor II (N-acetyl-leucyl-leucyl-methioninal)", <i>Cell. Calcium</i> , 18:1-8, 1995.
	C28	Braun <i>et al.</i> , "Identification of a new calpain-like cDNA in mouse lung," Database EMBL 'Online!', XP002139084 Abstract
	C29	Braun <i>et al.</i> , "Identification of a new calpain-like cDNA in mouse lung," Database EMBL 'Online!', XP002139083 Abstract
	C30	Cox <i>et al.</i> , "Loci on chromosomes 2 (NIDDM1) and 15 interact to increase susceptibility to diabetes in Mexican Americans," <i>Nature Genetics</i> , 21:213-215, 1999.
	C31	Terada <i>et al.</i> , "Delayed wallerian degeneration and increased neurofilament phosphorylation in sciatic nerves of rats with streptozocin-induced diabetes," <i>J Neuro Sci.</i> , 155:23-30, 1998.
	C32	Wang and Yuen, "Calpain inhibition: an overview of its therapeutic potential," <i>TIPS</i> , 15:412-417, 1994.
	C33	Saido <i>et al.</i> , "Calpain: new perspectives in molecular diversity and physiological-pathological involvement," <i>FASEB</i> , 8:814-822, 1994.

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	C34	Carafoli <i>et al.</i> , "Calpain: a protease in search of a function?," <i>Biochem. Biophys. Res. Commun.</i> , 247:193-203, 1998.

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